REMARKS

1. Claims

Prior to the present amendment, claims 3 and 10-15 are pending in the application, and claims 4-9 are cancelled.

In the current amendment, Claim 3 has been amended by insertion of the term "wherein said pharmaceutical composition contains 100 to 1800 nmol of C-peptide". The basis for the amendment can be found throughout the specification and particularly for example in claim 13 as originally filed, and on page 5, paragraph [0056] of the instant application. Claim 13 has been canceled, and a new claim 16 has been added. Claim 15 has been amended to change the claim dependency, so that it now depends on new claim 16.

New claim 16 is directed to the method of claim 3, wherein the diabetic conditions are selected from diabetic nephropathy, retinopathy or neuropathy. The basis for the new claim can be found throughout the specification, and particularly for example in claim 15 as originally filed, and on page 2, paragraph [0019] of the instant application.

The amendment and cancellation of the claims are not to be construed as acquiescence to any of the objections/rejections set forth in the instant office action, and were done solely to expedite prosecution of the application. No new matter has been inserted. Applicants reserve the right to pursue the claims as originally filed or similar claims, in this or one or more subsequent patent applications.

Entry of these amendments is requested under 37 CFR 1.116 because they will place the case in condition for allowance or in better form for appeal. Based on the amendment and following remarks, applicants respectfully request that the Examiner reconsider the outstanding rejections and that they be withdrawn.

1. Withdrawal of Certain Rejections.

Applicants acknowledge the withdrawal of the previous rejection of claims 3, 10 and 12-15 under 35 U.S.C. §102(b) as being anticipated by Johansson et al., Diabetologia, 35 121-128 (1992). Applicants also acknowledge the withdrawal of the previous rejections of claims 3, 10, and 12-15 under 35 U.S.C. §103 in view Johansson et al., as cited above, further in view of Wahren et al., (1998).

2. Acknowledgement of references

Applicants respectively request that the Examiner provides a signed acknowledgement of the IDS references provided by the applicants in the previous responses.

3. Rejection of claims 3, 10, 12 & 14 Under 35 U.S.C. § 102(b)

a) The Examiner rejects claims 3, 10, 12, and 14 under 35 USC § 102(b) as being unpatentable over Fernqvist-Forbes et al., (Diabetologia 36 (Suppl 1): A1-222, 1993, Abstract 483 on page A126). ("Fernqvist-Forbes et al."). Specifically the Examiner is of the opinion that because the terms "rate-controlling agents", "continuous administration" and "prolonged period of time" are not explicitly defined in the specification, and "absence specific guidance within the disclosure, the claim is interpreted as encompassing a once daily administration, by any mode other than osmotic pump and excluding infusions that go beyond the bounds of 24 hours ("daily" of the claims)." (See present Office Action, page 3). Accordingly the Examiner concludes that the claims fail to distinguish over Fernqvist-Forbes et al., which discloses a method comprising administering a single subcutaneous administration of 60 nmol/L of biosynthetic human C-peptide to type 1 diabetic human patients in a saline solution.

Applicants respectfully traverse the assertion that the claimed invention is anticipated by Fernqvist-Forbes et al., and solely to expedite the prosecution of the present case have amended claim 3 to incorporate the limitations of claim 13. Thus upon entry of the present amendment, claim 3, and all of the pending claims, include the limitation of claim 13.

Accordingly because all of the pending claims as currently amended include the limitation of claim 13, which the Examiner acknowledged on page 8, paragraph 11 of the Office Action, appears to be free of the prior art, and was not rejected under 35 USC §102(b), the currently amended claims are not anticipated by Fernqvist-Forbes et al. Specifically because Fernqvist-Forbes et al. neither discloses, or suggests that once daily subcutaneous administration of a pharmaceutical composition of C-peptide comprising 100 to 1800 nmol of C-peptide as currently recited in newly amended claim 3, it cannot anticipate independent claim 3, or dependent claims 10, 12 & 14, or newly introduced claim 16.

Accordingly applicants respectfully requests that the rejection of these claims under 35 U.S.C. § 102(b) over Fernqvist-Forbes et al. be reconsidered and withdrawn.

b) The Examiner rejects claims 3, 10, 12, and 14 under 35 USC § 102(b) as being unpatentable over Linde B., (Absorption of C-peptide after subcutaneous injection in type 1 diabetic patients, In: C-peptide and type 1 diabetes mellitus", An International Symposium, Karolinska Institute, Stockholm Sweden, September 23-24, 1994). ("the Linde reference"). Specifically the Examiner is of the opinion that as discussed above, the terms "rate-controlling agents", "continuous administration" and "prolonged period of time" are not explicitly defined in the specification, and because the claim language is open ended, the claim reads on the administration of other agents in combination with C-peptide. Accordingly the Examiner concludes that claims 3, 10, 12, and 14 are anticipated by the Linde reference which

discloses a method of administering a single subcutaneous administration of 60 nmol/L of biosynthetic human C-peptide to Type I diabetic human patients in a saline solution.

Applicants respectfully traverse the assertion that the claimed invention is anticipated by the Linde reference, and solely to expedite the prosecution of the present case have amended claim 3 to incorporate the limitations of claim 13. Thus upon entry of the present amendment, claim 3, and all of the pending claims include the limitation of claim 13.

Accordingly because all of the pending claims as currently amended include the limitation of claim 13, which the Examiner acknowledged appears to be free of the prior art, and was not rejected under 35 USC §102(b), the currently amended claims are not anticipated by the Linde reference. Specifically because the Linde reference neither discloses, or suggests the once daily subcutaneous administration of a pharmaceutical composition of C-peptide comprising 100 to 1800 nmol of C-peptide as currently recited in newly amended claim 3, it cannot anticipate independent claim 3, or dependent claims 10, 12 & 14, or newly introduced claim 16.

Accordingly Applicants respectfully requests that the rejection of these claims under 35 U.S.C. § 102(b) over the Linde reference be reconsidered and withdrawn.

c) The Examiner rejects claims 3, 10, 12, and 14-15 under 35 USC § 102(b) as being unpatentable over Wahren et al., (Journal of Internal Medicine, 240: 115-124, 1996). ("Wahren et al. 1996"). Specifically the Examiner is of the opinion that as discussed above, because the terms "rate-controlling agents", "continuous administration" and "prolonged period of time" are not explicitly defined in the specification, the claim is interpreted as encompassing a once daily administration, by any mode other than osmotic pump and excluding infusions that go beyond the bounds of 24 hours. Accordingly the Examiner concludes that claims 3, 10, 12, and 14-15 are anticipated by Wahren et al. 1996 which discloses a single subcutaneous administration of 60 nmol/L of biosynthetic human C-peptide to Type I diabetic human patients in a saline solution.

Applicants respectfully traverse the assertion that the claimed invention is anticipated by Wahren et al. 1996, and solely to expedite the prosecution of the present case have amended claim 3 to incorporate the limitations of claim 13. Thus upon entry of the present amendment, claim 3, and all of the pending claims include the limitation of claim 13.

Accordingly because all of the pending claims as currently amended include the limitation of claim 13, which the Examiner as acknowledged appears to be free of the prior art, and was not rejected under 35 USC §102(b), the currently amended claims are not anticipated by Wahren et al.1996. Specifically because Wahren et al. 1996 neither discloses, or suggests the once daily subcutaneous administration of a pharmaceutical composition of C-peptide comprising 100 to 1800 nmol of C-peptide

as currently recited in newly amended claim 3, it cannot anticipate independent claim 3, or dependent claims 10, 12 & 14, or newly introduced claim 16.

Accordingly Applicants respectfully requests that the rejection of these claims under 35 U.S.C. § 102(b) over Wahren et al.1996, be reconsidered and withdrawn.

4. Rejection of claim 11 Under 35 U.S.C. § 103(a).

The Examiner rejects claim 11 under 35 USC § 103(a) as being unpatentable over Fernqvist-Forbes et al., and further in view of Wahren et al., (1998) (cited in the last Office Action) ("Wahren et al 1998").

Specifically the Examiner is of the opinion that " One of ordinary skill in the art would recognize the use of the EGSLQ pentapeptide fragment, equivalent to claimed SEQ ID NO:2, taught by Wahren et al.1998 in the method of Fernqvist –Forbes et al. A skilled artisan would be motivated to combine the prior art elements because this specific fragment maintains the stimulatory activity and thus would result in the predictable effect of treating diabetic renal nephropathy. Based upon the guidance and direction within the prior art, such a combination would have been well within the technical grasp of a skilled artisan"

Applicants respectfully traverse the rejection and submit that the combination of references would not put one of ordinary skill in the art in possession of the claimed as currently amended, nor would one of ordinary skill in the art have any expectation of success in making the claimed invention based on the combination of references.

The Fernqvist –Forbes et al reference is discussed above, and there is nothing in Wahren et al.1998 either alone or in combination with the prior art as a whole that would make up for the deficiencies of the Fernqvist –Forbes et al. reference. Again, there is nothing in Fernqvist –Forbes et al. or the teachings of the prior art, including Wahren et al. 1998, that provides an expectation of success that suggests that once daily subcutaneous administration of a pharmaceutical composition of C-peptide comprising 100 to 1800 nmol of C-peptide would be therapeutically effective given the short biological half life of the C-peptide.

Accordingly the combination of references does not put one of ordinary skill in the art in possession of the claimed invention, and the Examiner has not established a prima facie case of obviousness with respect to claim 11 as currently amended. Accordingly Applicants respectfully requests that the rejection of claim 11 under 35 U.S.C. § 103 be reconsidered and withdrawn.

5. Conclusion

As discussed in previous responses, the discovery that a single daily dose of C-peptide is as effective as the administration of multiple daily doses (e.g. 3-4 times daily), or continuous administration is an extremely important and unexpected advance in the treatment of the microvascular complications of diabetes.

As acknowledged by the Examiner on page 8 of the Office Action, claim 13 is free of the art and would be allowable if written in independent form. The current amendment achieves this result, and accordingly it is respectfully requested that the current amendment be entered, and the case allowed.

In view of the above remarks, reconsideration and allowance of the application are respectfully requested. The Commissioner is authorized to charge any additional fees that may be required in connection with this submission, including petition fees and extension of time fees, or to credit any overpayments to Deposit Account No. 504297.

Respectfully submitted,

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Date

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Certificate of Electronic Filing

I hereby certify that the attached **Response to Office Action** and all marked attachments are being deposited by Electronic Filing on 05/25/2010 by using the EFS – Web patent filing system and addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: /Dennis A. Bennett/

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